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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/786,105 | 02/26/2001 | Robert Shipman | VGEN.P-055 | 8468 |

21121 7590 02/03/2003
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EXAMINER

CHUNDURU, SURYAPRABHA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1637

DATE MAILED: 02/03/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,105

Applicant(s)

SHIPMAN, ROBERT

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 15-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response to the office action (Paper No. 11) filed on November 12, 2002 has been entered.

Response to Arguments

3. Applicant's response to the office action (Paper No.11) is fully considered and found not persuasive.

4. Applicants' argument with respect to the maintained restriction requirement is fully considered and found not persuasive. Applicants argue that amended claim 1 in the instant invention does not support the X category reference (Kapur), further Applicants argue that the claim 1 is a non-elected claim, hence the restriction requirement based on X category reference is improper. This argument is fully considered and found not persuasive because first, the amended claim 1 is with in the scope of the category X reference. The amendment did not change the scope of the claim as compared to the claim 1 in the PCT application. Second, Applicants' elected of Group II (Claim 14) made the claim 1 as non-elected claim and non-examined claim. Therefore the argument that restriction requirement is improper is irrelevant in this context. Thus, the restriction requirement is deemed proper and maintained herein.

5. Applicants' argument with reference to the objection made in the previous office action regarding duplicate SEQ ID Nos. 3 and 4 is fully considered and found not persuasive.

Applicants' argue that the SEQ Nos. 1 and 2 are amplification primers, generally not labeled, and SEQ ID Nos. 3 and 4 are sequencing primers, generally labeled and hence are different. This argument is found not persuasive because, sequences in SEQ ID No. 1 is same as SEQ ID No. 3 and SEQ ID Nos. 2 is same as SEQ ID No. 4. The sequence search resulted in the same hits for

these SEQ IDs. The difference in the labeling can not be distinguished by sequence alignment search, if the sequences are absolutely same. Applicants did not show a difference in the sequences in these SEQ ID Nos. and hence the objection is maintained herein.

6. Applicants' argument with reference to the rejection made under 35 U.S.C. 112 second paragraph in the previous office action is fully considered and found not persuasive. Applicants' argue the phrase "at least one combination of primer pairs" is not indefinite and is within the scope of the knowledge of one having ordinary skill in the art. This argument is not persuasive because one having ordinary skill in the art could read the phrase two different ways. First, Combination could include SEQ ID No. 1 and 3 as at least one pair. Second, SEQ ID Nos. 1 and 3, and SEQ ID Nos. 2 and 4 (2 pairs) could be included which satisfies the phrase at least one. If both pairs are included, the identical sequences can not be distinguishable since the sequences in one pair are identical to the sequences in the other pair. Thus the phrase is confusing and indefinite.

Applicants' argument regarding the rejection based on non-elected species is fully considered and the rejection with reference to the non-elected species is moot.

7. Applicants' argument with reference to the rejection made in the previous office action under 35 USC 102(b) is fully considered and found not persuasive. As discussed above in response to the rejection under 35 USC 112, second paragraph, one primer pair satisfies the claim limitation. Further, the claim is of the open "comprising" format, which permits the inclusion of additional elements, so that any additional limitations are permitted in the claim. Therefore the rejection is maintained herein.

8. Applicants' argument with reference to the rejection made in the previous office action under 35 USC 103(a) is fully considered and found not persuasive. Applicants' argue that the specific

combination of primers of the instant invention are nonobvious and hence the general techniques described in the prior art of the record are not relevant to the present context. This argument is not persuasive because one having ordinary skill in the art would know how to design a primer or primers using the currently available techniques as described in the prior art. RpoB gene target sequence is known in the art and the general techniques to design a primer is obvious from the known sequence. Further, the claim is of the open "comprising" format, which permits the inclusion of additional elements, so that any additional limitations are permitted in the claim. The rpoB gene target comprises the primer sequences as claimed in the instant claim. Therefore the rejection is maintained herein.

Conclusion

No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-

Application/Control Number: 09/786,105
Art Unit: 1637

Page 5

1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

^{SPC}
Suryaprabha Chunduru
January 29, 2003



JEFFREY FREDMAN
PRIMARY EXAMINER